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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,893	10/27/2000	Morey Kraus	07588/008001	5973

21559 7590 02/28/2008  
CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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02/28/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/698,893	<b>Applicant(s)</b> KRAUS ET AL.	
	<b>Examiner</b> Anne-Marie Falk, Ph.D.	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007 and 02 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed November 1, 2007 (hereinafter referred to as “the response”) has been entered. Claims 1-3, 5-13, 15, 19-25, 27, 29-33, 35, 37, and 41-44 have been canceled and Claims 48-55 have been newly added.

Accordingly, Claims 48-55 are pending in the instant application.

The objection to the drawings is withdrawn in view of the new drawings filed November 1, 2007.

The objection to Claim 13 is withdrawn in view of the cancellation of the claim.

The rejection of Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for including new matter, is withdrawn in view of the cancellation of the claims. The newly added claims do not recite the new matter.

The rejection of Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the cancellation of the claims. The rejection is not applied to the newly added claims in view of the 37 CFR 1.132 Declaration of Dr. Kraus, filed November 2, 2007. The Declaration has been fully considered and is found to be generally persuasive with regard to the issues it addresses.

The rejection of Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of the cancellation of the claims and further in view of the 37 CFR 1.132 Declaration of Dr. Kraus, filed November 2, 2007.

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The rejection of Claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 under 35 U.S.C. 112, second paragraph, for indefiniteness, is withdrawn in view of the cancellation of the claims and further in view of the 37 CFR 1.132 Declaration of Dr. Kraus, filed November 2, 2007.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2007 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48-55 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2002/0028510 A1 (Sanberg et al.; published March 7, 2002; filed March 9, 2000), as evidenced by Rosu-Myles et al. (2000, Stem Cells 18: 374-381), for reasons of record as applied to the previously pending claims.

The claims are directed to a method of treating a human patient suffering from stroke.

Sanberg et al. (2000) disclose a method for treating stroke by administering umbilical cord blood cells. Claim 39 recites “a method of treating a patient with a neurodegenerative disease comprising administering an effective number of neural cells in umbilical cord blood or a mononuclear fraction thereof to said patient.” Claim 40 specifically recites treating ischemia. Claim 64 recites “a method of treating a patient in need thereof for a neurodegenerative disease other than amyotrophic lateral sclerosis, said method comprising administering an effective amount of human umbilical cord blood or a mononuclear cell fraction thereof to said patient.” Claim 65 specifically recites treating ischemia. The disclosure explicitly contemplates using the method of the invention to treat stroke (paragraphs [0042], [0054], [0065], and paragraphs [0161] through [0233]). The reference discloses significant functional recovery in a rat stroke model (paragraph [0231]).

The reference of Sanberg et al. inherently discloses administration of a cell composition comprising Lin<sup>-</sup> cells, as recited in the claims, because human cord blood cells inherently comprise Lin<sup>-</sup> cells, as evidenced by Rosu-Myles et al.

Thus, the claimed invention is disclosed in the prior art.

At pages 14-15 of the response, Applicants allege that Sanberg fails to teach or suggest the administration of isolated CD34<sup>+</sup>/Lin<sup>-</sup> cells to a patient for the treatment of stroke. However, Sanberg teaches the use of a mononuclear cell fraction isolated from umbilical cord blood and Rosu-Myles et al. provide evidence showing that this cell fraction does contain Lin<sup>-</sup> cells. Furthermore, there is nothing in the claims requiring a highly purified population of CD34<sup>+</sup>/Lin<sup>-</sup> cells, such that all other cell types are excluded, and the CD34<sup>+</sup>/Lin<sup>-</sup> cell composition described in the specification is not disclosed as being a homogeneous cell population, and is therefore understood to comprise a variety of other cell types. Accordingly, the cell composition used by Sanberg does include isolated CD34<sup>+</sup>/Lin<sup>-</sup> cells.

***Conclusion***

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/

Primary Examiner, Art Unit 1632